CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Assistant Commissioner for Patents, Arlington, VA 22202, on the date appearing below.
ELI LILLY AND COMPANY

By KSGriffiths Date 2-11-03

#12
M.Q.
2/27/03

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	: Janet M. Hock et al.	)
Serial No.	: 09/647,278	)
Filed	: September 26, 2000	) Group Art Unit: 1646
For	: Method of Increasing Bone Toughness and Stiffness and Reducing Fractures	)
Docket No.	: X-11965	) Examiner: R. Li

DECLARATION UNDER 37 C.F.R. 1.132

Assistant Commissioner for Patents
Arlington, VA 22202

Sir:

I, Kristi L. Griffiths, declare that:

I hold the degree of Doctor of Philosophy (PhD) in statistics.

I have been employed since June 1995 by Eli Lilly and Company as a Pharmaceutical Product Development Statistician.

I further declare that I have read US Patent 4,698,328 (hereinafter "Neer") and make the following statements about its contents.

1. Neer teaches administration of human PTH(1-34) to increase bone mineral density in osteoporosis patients.

2. Neer teaches administration of PTH(1-34) to osteoporosis patients in a dosage range of 100 Units to 700 Units activity.

3. Neer specifies use of the chick hypercalcemic assay to measure the activity of PTH(1-34).

4. Neer specifies use of an "International Reference Preparation of hPTHF 1-34" in assaying PTH(1-34) activity.

5. Neer does not provide a specific activity for PTH(1-34) that would allow conversion of Neer's units of PTH(1-34) activity to microgram quantities of PTH(1-34).

6. If the "International Reference Preparation of hPTHF 1-34" specified by Neer were not available, one could not determine the microgram equivalent of Neer's unit dosage, nor compare Neer to other published data.

7. I am unaware of any statistical basis for selecting a specific activity from the prior art to apply to Neer, since the activity of PTH(1-34) is dependant on the particular sample, assay method, and reference standard.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and may jeopardize the validity of the application or any patent issuing thereon.

Kirk L. Griffith
Declarant's Name

2/7/03
Date

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ELI LILLY AND COMPANY

By KS Rhoades Date 2-11-03

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Janet M. Hock et al.	)
Serial No.	:	09/647,278	)
Filed	:	September 26, 2000	) Group Art Unit: 1646
For	:	Method of Increasing Bone Toughness and Stiffness and Reducing Fractures	) Examiner: R. Li
Docket No.	:	X-11965	)

DECLARATION UNDER 37 C.F.R. 1.132

Assistant Commissioner for Patents
Arlington, VA 22202

Sir:

I, Bruce I. Meiklejohn, declare that:

I hold the degree of Doctor of Philosophy (PhD) in Chemistry.

I have been employed since February 1994 by Eli Lilly and Company in the following capacities: Team Leader of Biochemical Trace Analysis; Head of Analytical Chemistry; currently I am Director of Biopharmaceutical Product Development. For the past several years I have been actively involved in an World Health Organization (WHO) international effort to establish an appropriate international reference standard for human parathyroid hormone.

I am the inventor or co-inventor of one (1) United States patents.

I further declare that I have read US Patent 4,698,328 (hereinafter "Neer") and make the following statements about its contents.

1. Neer teaches administration of PTH(1-34) to osteoporosis patients in a dosage range of 100 Units to 700 Units activity.

2. Neer does not provide a specific activity for PTH(1-34) that would allow conversion of Neer's units of PTH(1-34) activity to microgram quantities of PTH(1-34).

3. Neer specifies use of an "International Reference Preparation of hPTHF 1-34" for assaying PTH(1-34) activity.

4. I am not aware of the existence of the specified "International Reference Preparation of hPTHF 1-34," cited by Neer.

5. I do not believe there currently is, or ever has been, an appropriate International Reference Standard for human PTH (1-34).

6. The need for a human PTH standard is currently being addressed by the World Health Organization (WHO). The WHO initiative involves laboratories from around the world, including Eli Lilly and Company, to establish an appropriate international reference standard for full-length human parathyroid hormone, i.e. human PTH(1-84). While Lilly applauds this effort as a necessary step in the right direction, it still leaves open the need for an appropriate international reference standard for human PTH(1-34). To this end, Lilly is presently engaging the WHO in a dialogue to take on a new initiative to establish an appropriate international reference standard for human PTH(1-34).

7. Without access to the *specific* standard cited by Neer it would be futile to try and compare Neer's Units dosage to other units dosages since the activity measurement of

PTH(1-34) is highly dependant on the particular assay and standard used.

I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both (18 U.S.C. 1001), and may jeopardize the validity of the application or any patent issuing thereon.

Bruce I. Meiklejohn

2/10/03
Date

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ELI LILLY AND COMPANY

By KSR-Loades Date 2-11-03

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Hock et al.
Serial No.	:	09/647,278
Filed	:	September 26, 2000
For	:	METHOD OF INCREASING BONE TOUGHNESS AND STIFFNESS AND REDUCING FRACTURES
Docket No.	:	X-11965

STATEMENT
UNDER 37 C.F.R. 1.48(c)(2)

Assistant Commissioner for Patents
Arlington, VA 22202
Sir:

The above-identified application was filed in the name of Janet M. Hock. In a prior response, dated January 29, 2002, Applicants submitted a petition to amend the inventorship in order to add the names of Gregory A. Gaich and Willard H. Dere, pursuant to 37 C.F.R. 1.48(c).

In accordance with the requirements of 37 C.F.R. 1.48(c)(2), the undersigned Gregory A. Gaich states that his addition as an inventor on the above-captioned case was necessitated by amendment of the claims and that the inventorship error occurred without deceptive intention on his part.

Gregory A. Gaich — 22 Jan 2003 Date

Applicants request favorable action on this petition.

Respectfully submitted,

Thomas D. Webster, PhD
Attorney for Applicants
Registration No. 39,872
Phone: 317-276-3334

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

February 11, 2003

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ELI LILLY AND COMPANY

By K S Rhoades Date 2-11-03

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant	:	Hock et al.
Serial No.	:	09/647,278
Filed	:	September 26, 2000
For	:	METHOD OF INCREASING BONE TOUGHNESS AND STIFFNESS AND REDUCING FRACTURES
Docket No.	:	X-11965

STATEMENT
UNDER 37 C.F.R. 1.48(c)(2)

Assistant Commissioner for Patents
Arlington, VA 22202
Sir:

The above-identified application was filed in the name of Janet M. Hock. In a prior response, dated January 29, 2002, Applicants submitted a petition to amend the inventorship in order to add the names of Gregory A. Gaich and Willard H. Dere, pursuant to 37 C.F.R. 1.48(c).

In accordance with the requirements of 37 C.F.R. 1.48(c)(2), the undersigned Willard H. Dere states that his addition as an inventor on the above-captioned case was necessitated by amendment of the claims and that the inventorship error occurred without deceptive intention on his part.

Willard H. Dere January 22, 2003

Willard H. Dere Date

Applicants request favorable action on this petition.

Respectfully submitted,

Thomas D. Webster, PhD
Attorney for Applicants
Registration No. 39,872
Phone: 317-276-3334

Eli Lilly and Company
Patent Division
P.O. Box 6288
Indianapolis, Indiana 46206-6288

February 11, 2003